



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,384	10/22/2003	Stephen P. Oliver	HME/7477.0017	8786
29085 7590 03/08/2007 HOWARD EISENBERG, ESQ. 1220 LIMBERLOST LANE GLADWYNE, PA 19035			EXAMINER DEVI, SARVAMANGALA J N	
			ART UNIT	PAPER NUMBER
			1645	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/08/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/691,384

Applicant(s)

OLIVER ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 22106, 122005, 31004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: Sequence reports (4 pages).

DETAILED ACTION

Election

1) Acknowledgment is made of Applicants' election filed 12/18/06 in response to the restriction mailed 09/28/06. Applicants have elected invention I, claims 1-5 and 11-14, drawn to a polypeptide comprising SEQ ID NO: 4. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P § 818.03(a)).

Status of Claims

2) Claims 1-45 are pending.

Claims 6-10 and 15-45 have been withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. 1.142(b) and M.P.E.P § 821.03.

Claims 1-5 and 11-14 are under examination. A First Action on the Merits is issued on these claims.

Information Disclosure Statements

3) Acknowledgment is made of Applicants' information disclosure statements filed 02/21/06, 12/20/05 and 03/10/04. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Sequence Listing

4) Acknowledgment is made of Applicants' raw Sequence Listing which has been entered 10/31/03.

Priority

5) The instant application claims priority to the provisional application 60/429,499, filed 12/26/02.

Specification

6) The specification is objected to for the following reason(s):

(a) To be accurate, the limitation 'Figure 1' at the bottom of page 4 of the specification should be replaced with the limitation --Figure 1A-1D-- to indicate the four panels within Figure 1.

(b) The use of trademark recitations in the instant specification has been noted. For example, see Example 6 for 'Sepharose' and 'Triton-X 100'. See Examples 11 and 12, and line 7 of page 24 for 'Tween-20'. See line 3 on page 17 for 'NeutrAvidin'. See the bottom of page 26 for 'Brownlee C18'. The recitations should be capitalized wherever they appear. See M.P.E.P 608.01(V) and Appendix I. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification to make similar corrections to trademark recitations, wherever such recitations appear.

(c) On page 16, line 12, the address of the American Type Culture Collection is incorrect. Effective 23 March 1998, ATCC has a new address: 10801 University Boulevard, Manassas, VA 20110-2209. Amendment to the specification is suggested to reflect this. It is suggested that Applicants examine the whole specification to make similar correction to the address, wherever it appears.

Rejection(s) under 35 U.S.C. § 112, First Paragraph (Scope of Enablement)

7) Claims 1-5 and 11-14 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a purified *Streptococcus uberis* SUAM polypeptide having the N-terminal amino acid sequence of SEQ ID NO: 4, or a purified pepSUAM, i.e., SEQ ID NO: 4, which binds to an antibody raised to said SUAM polypeptide, or to said pepSUAM conjugated to KLH, which antibody reduces the *in vitro* adherence and internalization of a bovine mammary epithelial cell line by two strains of *Streptococcus uberis* isolated from cows having clinical mastitis, does not reasonably provide enablement for an isolated polypeptide comprising an amino acid sequence that is at least 50%, 60%, 70%, 80% or 90% homologous with SEQ ID NO: 4 (i.e., a polypeptide variant), or for any 6 sequential amino acid-long, 7-10, 9-12 or 10-14 sequential amino acid-long polypeptide of SEQ ID NO: 4, where an antibody that binds to the polypeptide inhibits the adherence or internalization of *Streptococcus uberis* to bovine mammary cells, as claimed broadly. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the claims.

Instant claims are evaluated based on *Wands* factors. Many of the factors regarding undue

experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

- The quantity of experimentation necessary (time and expense);
- The amount of direction or guidance presented;
- The presence or absence of working examples of the invention;
- The nature of the invention;
- The state of the art;
- The relative skill of those in the art;
- The predictability or unpredictability of the art; and
- The breadth of the claims.

Instant claims are drawn to an isolated polypeptide comprising an amino acid sequence at least 50%, 60%, 70%, 80% or 90% homologous with SEQ ID NO: 4 (i.e., a polypeptide variant) or for any 6 sequential amino acid-long, 7-10, 9-12, or 10-15 sequential amino acid-long polypeptide of SEQ ID NO: 4 (i.e., a fragment of SEQ ID NO: 4), where an antibody that binds to the polypeptide inhibits the adherence or internalization of *Streptococcus uberis* to bovine mammary cells. The recited SEQ ID NO: 4 is fifteen amino acid-long and represents the N-terminal amino acid sequence of a 112 kDa *Streptococcus uberis* SUAM polypeptide. The claimed polypeptide variant is 50%, 40%, 30%, 20% or 10% non-homologous with SEQ ID NO: 4, and the claimed fragment of SEQ ID NO: 4 is shorter than 15 amino acids, i.e., 6, 7-10, 9-12 or 10-14 amino acid-long. Both are required to bind to an antibody that inhibits the adherence or internalization of *Streptococcus uberis* to bovine mammary cells. The limitation 'antibody' encompasses an antibody generated in a subject in response to the natural infection and an antibody raised in laboratory animals to the polypeptide variant or the polypeptide fragment. The limitation '*Streptococcus uberis*' encompasses homologous and heterologous *Streptococcus uberis*. The limitation 'at least 6', 'at least 7 to 10', or 'at least 10 to 15' sequential amino acids of SEQ ID NO: 4 encompasses six amino acid-long to 14 amino acid-long fragments of SEQ ID NO: 4, each having the recited functional property. The specification indicates diagnostic and prophylactic applications. In order for an antibody to bind to the claimed polypeptide variant or the polypeptide fragment, the variant or the fragment has to have a *Streptococcus uberis*-specific epitope or an antigenic determinant, which can be a linear or conformational epitope. The recited polypeptide variant that is at least 50% to 10% non-homologous with the fifteen amino acid-long amino acid sequence of SEQ ID NO: 4, or the claimed 6 to 14 amino acid-long fragment of SEQ ID NO: 4 is *required* to have this

antigenic determinant or epitope. The prophylactic and diagnostic applications described in the specification indicate that the claimed polypeptide that is at least 50% to 10% non-homologous to SEQ ID NO: 4, or the claimed fragment of SEQ ID NO: 4, is meant for use in the prophylaxis and diagnosis of homologous and heterologous *Streptococcus uberis* infections. However, there is not one single showing within the instant specification that a polypeptide variant that is at least 50% to 10% non-homologous to SEQ ID NO: 4, or the claimed 6 to less than 15 amino acid-long fragment of SEQ ID NO: 4, would retain one or more linear or conformational epitopes therein and/or the ability to bind an antibody that inhibits the adherence or internalization of *Streptococcus uberis*. The showing in the instant specification is limited to the production of antibodies to the purified 112 kDa SUAM polypeptide and the purified synthetic pepSUAM, i.e., SEQ ID NO: 4, the latter conjugated to KLH (see Example 10) and a showing that these antibodies to SUAM and pepSUAM reduce the *in vitro* adherence and internalization of the MAC-T bovine mammary epithelial cell line by two strains of *Streptococcus uberis* isolated from cows having clinical mastitis (see Example 13). Other than this, not a single polypeptide variant species (let alone a representative number of variant species) having at least 50% to 10% non-homology to SEQ ID NO: 4 is shown within the instant specification to bind to an antibody that inhibits the adherence or internalization of homologous or heterologous *Streptococcus uberis* to bovine mammary cells *in vitro* or *in vivo*. This is important because an epitope or antigenic determinant on an antigen is known to bind to antibodies via a three-dimensional fit. See pages 58 and 59 of Herbert *et al.* (*The Dictionary of Immunology*, Academic Press, 3rd Edition, London, pages 58-59, 1985). This means that the antigenic determinant in Applicants' polypeptide variant that has at least 50% to 10% non-homology to SEQ ID NO: 4, or Applicants' 6-14 amino acid-long fragment, has to have the three dimensional configuration in order to bind to an antibody that inhibits the adherence or internalization of homologous or heterologous *Streptococcus uberis* to bovine mammary cells. However, the instant specification lacks evidence or guidance with regard to this. Therefore, the full scope of the instant claims is not enabled. There is absolutely no showing of a correlation between the primary or tertiary structure of a polypeptide variant that has at least 50% to 10% structural non-homology with SEQ ID NO: 4 or a 6-14 amino acid-long fragment thereof, and its ability to bind to an antibody that inhibits the adherence or internalization of homologous or heterologous *Streptococcus uberis* to bovine mammary cells *in vitro* or *in vivo*. There is no showing

that the polypeptide variants encompassed within the scope of the claims tolerate modifications and remain antigenic and retain the ability to bind an antibody that inhibits the adherence or internalization of *Streptococcus uberis*. The instant specification does not identify the precise six, seven, eight, nine etc. amino acid-long fragment of SEQ ID NO: 4 that binds to an antibody that inhibits the adherence or internalization of *Streptococcus uberis*. With this lack of showing, the Office would look into the literature in the relevant art of polypeptide variants or peptide fragments in order perform the required *Wands* analysis.

A review of the state of the art at the time of the invention, particularly with regard to the unpredictability factor as associated with bacterial proteins, documents the following. The art shows that an alteration even in a single amino acid can eliminate or drastically change one or more biologic function(s) of the polypeptide. For instance, McGuinness *et al.* (*Lancet* 337: 514-517, March 1991) showed that a point mutation generating a single amino acid change in a P1.16-specific epitope in the VR2 region of the *porA* gene of a strain of *Neisseria meningitidis* of subtype P1.7,16 resulted in "striking changes in the structural and immunological properties of the class 1 protein" of this isolate (see abstract and page 514). With particular reference to VR1 and VR2 peptides of class 1 outer membrane protein of *Neisseria meningitidis*, McGuinness *et al.* (*Mol. Microbiol.* 7: 505-514, Feb 1993) also taught that "[a] single amino acid change *within an epitope*, or an amino acid deletion *outside an epitope*, were both associated with *loss of subtype specificity* resulting from a change in the predicted conformation at the apex of the loop structure" (see abstract) [Emphasis added]. One of skill in the art can reasonably expect a loss of immunospecificity to '*Streptococcus uberis*' in Applicants' polypeptide variant since it has up to 50% non-homology to the amino acid sequence of SEQ ID NO: 4. It should be noted that Applicants have neither identified a functional site, i.e., an antigenic determinant, in a single polypeptide variant that is 50% to 10% non homologous to the amino acid sequence of SEQ ID NO: 4 that binds to an antibody that inhibits the adherence or internalization of *Streptococcus uberis*, for one of skill in the art to avoid or to include mutation(s) or variation(s) within or outside the antigenic determinant. The lack of disclosure and specific guidance within the instant specification combined with the art-recognized functional unpredictability would require one of skill in the art to engage in considerable amount of undue experimentation.

With regard to the structure-function relationship of an amino acid sequence in general,

Rudinger *et al.* (In: *Peptide Hormones*. (Ed) JA Parsons, University Park Press, June 1976) taught that 'the significance of particular amino acid sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study' (see page 6). Rudinger *et al.* further taught that 'it is impossible to attach a unique significance to any residue in a sequence' and that a 'given amino acid will not by any means have the same significance in different peptide sequences (i.e., fragments), or even in different positions of the same sequence (see page 3). The lack of guidance within the instant specification in combination with Rudinger's teachings supports the Office's position regarding the unpredictability factor and the need to engage in considerable amount of undue experimentation.

The state of the art on microbial polypeptides in general indicates that a random replacement affecting the epitopic amino acid positions that are critical to the three-dimensional conformational structure and specific binding property of a protein, would result in a polypeptide that may be non-functional, or not optimally antigenic as a diagnostic reagent, or not optimally immunogenic as a vaccine candidate, because such positions tolerate no or little modifications. For instance, Houghten *et al.* (New Approaches to Immunization, *Vaccines*86, Cold Spring Harbor Laboratory, p. 21-25, 1986) teach the criticality of individual amino acid residues and their positions in peptide antigen-antibody interactions. Houghten *et al.* state (see page 24):

One could expect point mutations in the protein antigen to cause varying degrees of loss of protection, depending on the relative importance of the binding interaction of the altered residue. A protein having multiple antigenic sites, multiple point mutations, or accumulated point mutations at key residues could create a new antigen that is precipitously or progressively **unrecognizable by any of the antibodies in the polyclonal pool.** [Emphasis added].

Thus, it has already been established in the art that variations in critical residues at specific positions of an amino acid sequence could result in a polypeptide variant, which may induce an antibody that may *not* recognize or bind to the native polypeptide of a microorganism. There is no predictability that a polypeptide variant having up to 50% sequence non-homology with the native polypeptide of SEQ ID NO: 4 would remain antigenically immunospecific to homologous or heterologous isolates of *Streptococcus uberis*.

The above-cited references reasonably demonstrate that even a single amino acid substitution/deletion will often dramatically affect the immunospecific biological activity or characteristics of a protein or polypeptide. Clearly, with up to 50% sequence non-homology to the

polypeptide of SEQ ID NO: 4, the *Streptococcus uberis*-specific antigenic function of the claimed polypeptide variant cannot be predicted, merely based on the sequence homology with SEQ ID NO: 4, nor would it be expected to be nearly the same as that of the polypeptide of SEQ ID NO: 4. The same holds true with the claimed polypeptide fragment. Although a skilled artisan might envision making a number of changes in the reference polypeptide sequence of SEQ ID NO: 4 in accordance with Applicants' disclosure, it is highly uncertain or unpredictable that the polypeptide variant as claimed would retain the ability to bind to an antibody that inhibits the adherence and internalization of *Streptococcus uberis*. If one nucleotide base in the nucleotide sequence that encodes the polypeptide of SEQ ID NO: 4 is deleted or inserted at a single position within the coding sequence, all the codons downstream of that insertion or deletion would be frame-shifted. If that frame-shift took place near the 5' end of the gene, it is likely that the varied polypeptide expressed will have little in common structurally or functionally with the native polypeptide that comprises SEQ ID NO: 4. The polynucleotide homologs or variants isolated solely based on percent identity or homology do not predictably display the functions of the native molecules, absent an independent showing that the variant polynucleotide sequence produces a polypeptide variant that functions as recited. The antigenic or binding functions of a gene product based solely on percent sequence identity is unreliable and unpredictable, absent a supportive showing by production of a representative number of 50 to 10% non-homologous polypeptide variant species that have the recited and required ability to bind to an antibody that inhibits the adherence and internalization of *Streptococcus uberis* to bovine mammary cells. For the reasons delineated above, making and using of the instantly claimed polypeptide variant or fragment having the recited ability to bind to an antibody that inhibits the adherence and internalization of *Streptococcus uberis* to bovine mammary cells *in vivo* or *in vitro* is well outside the realm of routine experimentation. Accordingly, undue experimentation would have been required by one of ordinary skill in the art at the time of the effective filing date of the instant application to reproducibly practice the invention as claimed, due to the lack of specific guidance, the lack of enabling disclosure, the art-demonstrated functional unpredictability as reflected in the state of the bacterial or microbial polypeptide art, the breadth of the claims, and the quantity of experimentation necessary. The claims are viewed as not meeting the scope of enablement provisions of 35 U.S.C § 112, first paragraph.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

- 8) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

- 9) Claims 1-5 and 11-14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claims 1 and 11 are vague and indefinite in the limitation: 'wherein an antibody that binds to the polypeptide cells', because it is unclear what function is associated with the claimed polypeptide. Is the limitation identified above a function of the recited antibody as opposed to the function of the claimed polypeptide?

(b) Claims 2-5 and 12-14, which depend from claim 2 or 11, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 102

- 10) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 11) Claims 1 and 11 are rejected under 35 U.S.C. § 102(b) as being anticipated by Drmanac *et al.* (WO 01/75067 – Applicants' IDS).

Drmanac *et al.* taught an isolated polypeptide comprising an amino acid sequence having 57.5% sequence homology to the instantly recited amino acid sequence of SEQ ID NO: 4. See the sequence with the accession number ABG03918 in the attached sequence alignment report; and see abstract; and claims 10 and 11 of Drmanac *et al.* The prior art polypeptide contains the at least six sequential amino acids KLQGEE of the instantly recited SEQ ID NO: 4. The prior art sequence KLQGEE is the same as the amino acids 9 to 14 in SEQ ID NO: 4 of the instant invention as identified at lines 2-6 of page 9 of the instant specification. Because the prior art polypeptide is structurally the same as the instantly recited polypeptide, it is expected to necessarily bind to an antibody that inhibits the adherence or internalization of *Streptococcus uberis* to bovine mammary

cells, absent evidence to the contrary.

Claims 11 and 12 are anticipated by Drmanac *et al.*

12) Claims 11 and 12 are rejected under 35 U.S.C § 102(b) as being anticipated by Alexandrov *et al.* (EP 1033405).

Alexandrov *et al.* taught an isolated amino acid sequence comprising at least seven sequential amino acids KLQGEEA of the instantly recited SEQ ID NO: 4. See the attached sequence alignment report. The prior art sequential amino acids KLQGEEA comprises the 9 to 14, or 10 to 15 amino acids from the instantly recited SEQ ID NO: 4, and therefore is the same as amino acids 9 to 14, or 10 to 15 in SEQ ID NO: 4 of the instant invention as identified at lines 2-6 of page 9 of the instant specification. Because the prior art polypeptide is structurally the same as the instantly recited polypeptide, it is expected to necessarily bind to an antibody that inhibits the adherence or internalization of *Streptococcus uberis* to bovine mammary cells, absent evidence to the contrary.

Claims 11 and 12 are anticipated by Alexandrov *et al.*

13) Claims 1-5 and 11-14 are rejected under 35 U.S.C § 102(b) as being anticipated by Park *et al.* (In: *Proceedings of the 40th Annual Meeting of National Mastitis Council*, National Council Incorporated, pages 247-248, February 2001).

Park *et al.* taught an isolated 110 or 112 kDa protein (i.e., polypeptide) from ATCC 13387, UT888, UT366, or UT102 strain of *Streptococcus uberis*. The polypeptide was purified by an SDS extraction method that is identical to the method described in Example 4 of the instant specification for the isolation and purification of the 110 kDa or 112 kDa protein of the instant invention that contains the amino acid sequence of SEQ ID NO: 4, i.e., MTTADQSPKLQGEEA, as described in Example 7 of the instant specification. Although Park *et al.* are silent about the amino acid composition of the N-terminal sequence of their *Streptococcus uberis* 112 or 110 kDa protein or polypeptide, the amino acid sequence as recited is viewed as an inherent feature of Park's isolated *Streptococcus uberis* 112 or 110 kDa polypeptide which was already known in the prior art. Because of the overlapping molecular weight, the *Streptococcus uberis* origin of the prior art polypeptide, the identical *Streptococcus uberis* ATCC13387 strain from which it was extracted by the identical SDS extraction method, the prior art polypeptide is viewed as the same as the isolated

polypeptide claimed in the instant claims, and therefore it is expected to have the same intrinsic structure and properties as that of the Applicants' polypeptide. The Office's position that the prior art polypeptide is the same as Applicants' polypeptide is based upon the fact that every characteristic overlapping in the prior art polypeptide and the Applicants' polypeptide are the same. In spite of the fact that the prior art fails to teach the disclosed functional characteristic of the Applicants' polypeptide, there is sufficient overlap to reasonably conclude that the prior art polypeptide is one and the same as the Applicants' polypeptide. The property of binding to an antibody that inhibits the adherence or internalization of *Streptococcus uberis* to bovine mammary cells is an intrinsic function inseparable from the polypeptide of the prior art.

Claims 1-5 and 11-14 are anticipated by Park *et al.*

Objection(s)

14) Claims 1-5 and 11-14 are objected to for the incorrect recitation 'Seq. ID No.' as opposed to --SEQ ID NO: --.

Remarks

15) Claims 1-5 and 11-14 stand rejected.

16) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number, (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

17) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

18) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

Application/Control No. 10/691,384
Art Unit: 1645
March 2007

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

March, 2007


S. DEVI, PH.D.
PRIMARY EXAMINER